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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,941	01/25/2002	Daniele Venturini	213653	8712

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[REDACTED] EXAMINER

PHILOGENE, PEDRO

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

3732

DATE MAILED: 05/20/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/937,941	VENTURINI, DANIELE
	Examiner Pedro Philogene	Art Unit 3732
<i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i>		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.		
<ul style="list-style-type: none"> - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). 		
Status		
1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>31 March 2003</u> .		
2a) <input checked="" type="checkbox"/> This action is FINAL . 2b) <input type="checkbox"/> This action is non-final.		
3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims		
4) <input checked="" type="checkbox"/> Claim(s) <u>2-11</u> is/are pending in the application.		
4a) Of the above claim(s) _____ is/are withdrawn from consideration.		
5) <input type="checkbox"/> Claim(s) _____ is/are allowed.		
6) <input checked="" type="checkbox"/> Claim(s) <u>2-11</u> is/are rejected.		
7) <input type="checkbox"/> Claim(s) _____ is/are objected to.		
8) <input type="checkbox"/> Claim(s) _____ are subject to restriction and/or election requirement.		
Application Papers		
9) <input type="checkbox"/> The specification is objected to by the Examiner.		
10) <input type="checkbox"/> The drawing(s) filed on _____ is/are: a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action.		
12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.		
Priority under 35 U.S.C. §§ 119 and 120		
13) <input type="checkbox"/> Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) <input type="checkbox"/> All b) <input type="checkbox"/> Some * c) <input type="checkbox"/> None of: 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.		
14) <input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.		
15) <input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.		
Attachment(s)		
1) <input type="checkbox"/> Notice of References Cited (PTO-892)		
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)		
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.		
4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .		
5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)		
6) <input type="checkbox"/> Other: _____ .		

Claim Objections

Claim 8 is objected to because of the following informalities: claim 8 depends on claim 1 which is a cancelled claim; so, for purpose of examination claim 8 would be considered as depending on claim 11. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11, 2-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gustilo (4,463,753) in view of Grossberndt (4,544,313).

With respect to claim 11, Gustilo discloses a bone screw for use in orthopaedic surgery with external fixation devices comprising a head (11, FIG.3) a shank (3, FIG.2) and a threaded portion (2, FIG.2) having an outside diameter and a core diameter which tapers towards a tip, as best seen in FIG.2, at an end opposite from the head (11, FIG.2) the thread portion (tapering towards the tip) having at least one constant pitch section, as set forth in column 5, lines 6-7, the threaded portion having threads formed with an acute angle, as set forth in column 5, lines 32-54; generally triangular cross sectional profile; as best seen in FIG.2.

It is noted that Gustilo did not teach of threads that are separated from each other by a shaped bottom land having a concave profile defined by two counter-sloping planes; as claimed by applicant. However, in a similar art, Grossberndt evidences the

use of a screw with threads that are separated from each other by a shaped bottom land having a concave profile defined by two counter-sloping planes to create surfaces to allow material that is being removed to slide during threads penetration, as a result the supporting force is increased, thereby releasing stress on the material.

Therefore, given the teaching of Grossberndt, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the special shape of the bottom land of Grossberndt in the device of Gustilo to create surfaces to allow material that is being removed to slide during threads penetration, as a result the supporting force is increased, thereby relieving material stress or, in this case, bone stress.

Although Grossberndt taught of threads having a constant height with a ratio of the outside diameter to the core diameter, it is noted that the above combination of references did not teach of a ratio range of 1.43 to 1.60; as claimed by applicant. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to reach the optimum range, since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

With respect to claims 2, 3, 4, 6, 7, Grossberndt teaches all of the limitations, as set forth. An obtuse angle of 120 degree (since applicant's specification stated that the obtuse angle is in the range of 120 to 150 degrees, therefore, the angle could only be at least 120 degrees and the most 150 degrees); the facing wall or shaped bottom land

having an acute angle in the 15 to 30 degrees range, column 3, line 1; and as best seen in FIGS. 1,2.

With respect to claims 5, 8,9,10, it is noted that the above combination of references did not teach of a screw having constant pitch of 1.25mm or a threaded portion one third the length of the screw or the height of the threads three fifths the pitch length wherein the height is 0.75mm; as claimed by applicant. However, applicant fails to establish the criticality of such dimensions and whether the limitations asserted in these claims are disclosed as critical, and if so, whether the invention disclosed in each claim, so limited; the examiner believes that any dimensions could have been used, since the device would have performed equally as well with any given dimensions.

Response to Amendment

Applicant's arguments filed 3/31/03 have been fully considered but they are not persuasive. Applicant stated that Grossberndt discloses threads the height of which reduces continually toward the end of the screw; instead applicant's attention is directed toward Gustilo where the height of the threads is constant. In response to applicant's argument that that 'the prior art, furthermore, lacks appreciation for the problem or solution to which applicant's invention is directed" a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a

manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (703) 308-2252. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P Shaver can be reached on (703) 308-2582. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 305-3591 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Pedro Philogene
May 16, 2003

Pedro Philogene
PEDRO PHILOGENE
PRIMARY EXAMINER